ELI LILLY - JAN. 15, 2009

Good morning.

We are here today to announce the resolution of a healthcare case that is history making, both in terms of the resolution itself and in its potential impact on how pharmaceutical companies market their products.

- We are announcing the largest combined civil and criminal resolution of any case against a single defendant in the history of the United States Department of Justice.

- The pharmaceutical company Eli Lilly has agreed to pay a total of more than one point four billion dollars – 615 million to resolve the criminal aspects of the case and nearly 800 million in the civil settlement.

- Eli Lilly company is also pleading guilty to the criminal misdemeanor charge of misbranding its drug Zyprexa, because the company illegally marketed this drug.

Zyprexa was approved by the Food and Drug Administration – the FDA – for the treatment of schizophrenia and related disorders, and for some types of bipolar disorder.

- Those were the only uses approved by the FDA.

- Eli Lilly has admitted that, in violation of federal law, it marketed Zyprexa to the elderly for such things as sleep disorders and dementia – conditions for which the drug was never approved.

- This “off-label” marketing put patients - particularly the elderly - at substantial risk, and undermined the FDA’s critical role in assuring that pharmaceuticals in the United States are safe and effective.

In this case, we are holding a company responsible for putting thousands and thousands of patients at risk, and we are sending a message to the entire pharmaceutical industry that the Department of Justice, and this office in particular, takes the offense of off-label marketing very seriously.

These are not easy cases to bring.

- This large group of extraordinary attorneys and agents, from an alphabet soup of government agencies,
is your visual representation of just how much effort
goes into investigating and resolving these cases.

- We are all committed to protecting patients by maintaining the integrity of the FDA's approval process for prescription drugs.

- With cases like this one, we hope to put an end to the unsafe practice in the pharmaceutical industry known as "off-label marketing."

Let me take a minute to explain what "off-label marketing" really is.

- By law, all prescription medications come with labeling, which includes the drug's intended uses and the directions for use.

- The FDA has in place an exhaustive process, which requires scientific testing, through which it approves drugs for specific purposes.

- The FDA approves a drug only for uses for which the drug is safe and effective.

- The approved uses are then contained on the label for the drug.

- When a drug is prescribed for one of the approved uses, like Zyprexa for schizophrenia, the drug is being prescribed "on label."

Now a doctor, making a careful and independent judgment on a patient-by-patient basis, may decide for a certain patient to prescribe a drug off-label - meaning to prescribe the drug for a non-FDA-approved use.

- Doctors are given this authority so that they have more options in how they exercise their own medical judgment on how to best treat a particular patient.

- It is a violation of federal law, however, for a drug company to urge doctors to off-label prescribe a drug for unapproved uses.

Eli Lilly completely ignored this law and crafted entire marketing campaigns, involving an army of thousands of sales representatives and glossy marketing brochures, aimed at convincing doctors to prescribe Zyprexa on a widespread basis for a whole range of unapproved uses.

Let me be more specific about what Eli Lilly did to make as much money as possible - hundreds of millions of dollars - from its drug Zyprexa.

- In 1995, Eli Lilly sought FDA approval of the drug for schizophrenia.
- The FDA gave that approval in September of 1996.
- And later, in 2000, the FDA also approved the use of Zyprexa for certain types of bipolar disorder
- In November of 1996, less than two months after the drug was first approved, the FDA was already cautioning Eli Lilly by letter that the company's promotional materials and activities were false and misleading in the way that the company was targeting the elderly.
- Especially misleading was the way that the company claimed that a potentially serious adverse event, namely weight gain which increases the risk of diabetes, was what the company called a "therapeutic benefit" of the drug.
- In 2004, the FDA added a warning to the label to address the concern about Zyprexa causing hypoglycemia which can lead to coma or even death.
- In 2006, the FDA went even further and put its most serious possible warning - a so-called "Black Box" warning on the label - about the risk of giving Zyprexa to elderly patients with dementia.
- The FDA warning said there is an increased risk of death and that "Zyprexa is not approved for the treatment of patients with dementia-related psychosis."
- Zyprexa has never been approved for the treatment of dementia.
- In fact, the management of Eli Lilly made a specific decision not to seek FDA approval of the drug for dementia because the scientific studies would not support approval.

Regrettably, however, starting in 1999, the company undertook marketing campaigns to urge doctors to prescribe Zyprexa for a whole list of unapproved uses - not only dementia but also Alzheimer's disease, sleep disorders, depression, anxiety, and common behaviors such as hostility, aggression, and agitation.

Eli Lilly was concerned in the late 1990s about reduced revenue when it lost the patent on its drug Prozac, so the company was determined to greatly expand the market for Zyprexa.

- There was a company-wide effort to off-label market Zyprexa.

- The elderly, in particular, were targeted in the marketing campaigns.

- The company trained its sales force to disregard the law and to promote the drug off-label.

One strategy was to shift the focus of the sales representatives away from psychiatrists.

- Psychiatrists are the type of doctors likely to be treating the conditions for which Zyprexa was approved.

- Yet the company developed elaborate marketing campaigns targeted at primary care physicians and at the caregivers for the elderly in long-term care facilities.

- Only a very small number, less than one percent, of the elderly suffer from schizophrenia, an approved use for Zyprexa.

- But 60 to 80% of the elderly in care facilities suffer from some dementia.

- So the company decided to off-label market the drug as a treatment for dementia in the elderly.

At a large sales meeting in 2000 in Orlando, the company rolled out the "Viva Zyprexa" campaign.

- The management of the company told the hundreds of sales representatives there not to focus on conditions like schizophrenia, but on far more common patient symptoms such as depression.

- The company created slick campaigns with profiles on fictitious patients who could allegedly benefit from Zyprexa.

- One full-color visual aid for the sales representatives profiled a patient named "Rose Jackson."

- Rose did not suffer from schizophrenia or bipolar disorder.

- Eli Lilly's model patient for Zyprexa was an elderly woman who "requires extra time" and displays "aggressive behavior."

In addition to these patient profiles, the non-medically trained sales representatives used the slogan "five at five" - meaning five milligrams of Zyprexa at five o-clock in the evening, would keep an elderly, agitated patient quiet all night and not bothering the nursing staff or the doctors.

Eli Lilly's "off-label" promotion of Zyprexa raised safety issues, affected the treatment of patients, and undermined the FDA drug approval process.

- The company made hundreds of millions of dollars by trying to convince healthcare providers that Zyprexa was safe and effective for unapproved uses and, in the process of doing so, the company risked the health and lives of patients.

Off-label promotion can lull a physician into believing that a drug being promoted has FDA approval and is safe and effective for the intended off-label use.

- The marketing can also cause a doctor and patient to forgo treatment with a drug that has been approved and to, instead, substitute a treatment urged by the sales representatives but which might be ineffective and harmful.

Off-label marketing circumvents the very process put in place to protect the public.

- Taking medication for an unapproved use can be dangerous, even deadly.

- Here, the FDA warned that Zyprexa increases the risk of death in older patients with dementia.

This is the second criminal and civil resolution of an "off-label" marketing case in the Eastern District of Pennsylvania since September, when we reached a $425 million settlement with Cephalon for its alleged "off-label" promotion of the powerful painkiller Actiq.

- We are not trying to prevent pharmaceutical companies from conducting legitimate business.

- Nor are we trying to hamstring physicians, because we know that breakthrough drugs can relieve pain and improve a patient's quality of life.

But we must make sure that pharmaceutical companies market their drugs legally, because the process by which the FDA approves drugs for use and the established rules for marketing those drugs are designed to protect all of us.

- Pharmaceutical companies seeking to increase profits will not be allowed to ignore the law and to put patients at risk.

Before turning over the podium, I would like to thank
- Ed Bradley and his agents at the Defense Criminal Investigative Service
- Kim Rice and his agents at the Food and Drug Administration
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- the many state Deputy Attorney Generals who have made such an effort to be with us today
- Greg Katsas, the Assistant Attorney General for the Civil Division, and his attorneys
- Gene Thiroff and his attorneys, Jeff Steger and Ross Goldstein, at the Office of Consumer Litigation

- and the incredible team here in my office: Assistant United States Attorneys Marilyn May, Denise Wolf, and Joe Trautwein, and their supervisors Cathy Votaw, Linda Hoffa, Ginny Gibson, Peg Hutchinson, and Rich Zack, as well as our auditors Allison Barnes and Denis Cooke.